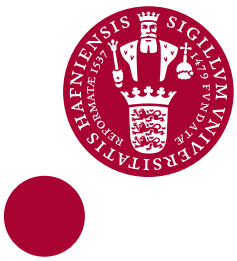

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The grand finale of a juicy European patents tale?

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The Impact of Broccoli II & Tomato II on European patents in conventional breeding, GMO's and Synthetic Biology: The grand finale of a juicy patents tale?

Timo Minssen* & Ana Nordberg**

Abstract:

On 25 March 2015, the Enlarged Board of Appeal of the European Patent Office (EBA) finally delivered its' much awaited decisions on the consolidated referrals G2/12 ("Tomato II") and G2/13 ("Broccoli II"). The EBA affirmed that products, namely plants or parts thereof, obtained by essentially biological processes are – unlike individual plant varieties – principally patentable under the European Patent Convention (EPC). This decision leaves considerable leeway for patenting novel and inventive plants and products thereof, which have been produced by "conventional" methods including breeding steps. The EBA has also clarified that this applies irrespective of if such claims are formulated in a product-by-process format or as a per se product . Moreover, the combined effect of Broccoli & Tomato I & II opens new opportunities for patenting GMOs - provided that all other patent criteria are also met. This generally appears to be "good news" for innovative plant breeders and agrochemical companies. However, caveat needs to be added: Major industry players had challenged the relevant patent-claims and the EBA's decision(s) remain very controversial. It is, for example, very uncertain how the CJEU would decide if confronted with similar issues in the context of national implementations of the Biotech Directive, which have taken a very different view than the EBA. Moreover, the fierce European opposition against genetically modified organisms (GMOs) and Synthetic Biology remains a major challenge to the industry, research and innovation in an increasingly significant area of science and debate.

Please note that recent developments until July 2017 have been added in a Post Scriptum section.

Introduction

For several years, the European patent and plant science communities have been captivated by a long, controversial and sometimes even emotional tale, featuring in the leading roles the so-called "Broccoli" and "Tomato" patents. On March 25, 2015, the EBA of the European Patent Office (EBA) delivered its much awaited decisions on the consolidated referrals G2/12 ("Tomato II") and G2/13 ("Broccoli II"), clarifying the exclusion from patentability of essentially biological processes, such as conventional crossing and selection, and in particular its impact on the patentability of claims for products resulting from such processes. The so-called "Tomato II" case

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concerned an invention entitled "method for breeding tomatoes having reduced water content and product of the method,"[1] whereas the so-called "Broccoli II" case involved an invention of a "method for selective increase of the anticarcinogenic glucosinolates in brassica species".[2]

The first chapter of this complex cases - 'Broccoli I' and 'Tomato I' - clarified issues regarding the patentability of genetically modified organisms. As a result, claims to transgenic plants (or animals) generally do not face objections under Article 53 (b) EPC[3] as long as these are carefully drafted at a higher taxonomic level, i.e. higher than a single plant variety, and even if such claims may embrace plant or animal varieties.[4] On the contrary, claims directed to individual plant or animal varieties or essentially biological processes for the production of plants, including steps of conventional methods for the breeding of plant varieties, had been generally held non-patentable.[5] However, it still remained to be determined, whether Article 53 (b) EPC also excluded the patentability of product claims and so-called *product-by-process* claims resulting from such excluded processes.

In "Tomato II" and "Broccoli II" the EBA finally confirmed unambiguously that plants or seeds obtained through such excluded processes are – in contrast to individual plant varieties patentable. Moreover, the EBA clarified that this applies even if such claims are formulated in a *product-by-process* format. Although major industry players had challenged the relevant patent-claims, the outcome is generally favourable to innovative plant breeders and agrochemical companies. As we will point out further below, it might even affect GMOs and Synthetic Biology, due to the increasing combination of conventional and microbiological techniques. So these stakeholders appear at least to have won a battle, but have they won the war?

After all, it should be remembered that relentless European and global opposition against the patentability of plants and plant material produced by conventional methods persists. This is also reflected by the decision of several national legislators to explicitly exlude the patentability of such products. Moreover,vigorous protests against the patentability and commercialization of genetically modified organisms (GMOs) and Synthetic Biology remain a major obstacle to the development of the industry, research and innovation in this increasingly relevant sector.

The persisting controversy is also reflected in the major disparities that still exist among different jurisdictions on both the European and international level. Notwithstanding an overall tendency towards worldwide harmonization in patent law, this crystallizes in particular in the context of biotechnological inventions.[6] In this area the TRIPS agreement stimulates a diverse development of the law and permits TRIPS member states to employ various options to various

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[1] Decision of the Enlarged Board of Appeal of 25 March 2015, G 2/12, available at <https://register.epo.org/application?documentId=EXBZW10W4599684&number=EP00940724&lng=en&npl=false> (accessed 20 May 2015).

[2] Decision of the Enlarged Board of Appeal of 25 March 2015, G 1/13, available at: <https://register.epo.org/application?documentId=EXBZX31D2974684&number=EP99915886&lng=en&npl=false> (accessed 20 May 2015).

[3] In this paper we mainly address issues pertaining to patentability of plants and plant material, however it should be noted that Article 53 (b) EPC also applies to the animal kingdom, and thus some of our conclusions may equally apply to genetic modified non-human animals.

[4] G 2/07 *Broccoli/Plant Bioscience* OJ EPO 2012, 130 and G 1/08 *Tomatoes/State of Israel*, OJ EPO 2012, 130. *See* also Decision of the Enlarged Board of Appeal dated 20 December 1999 in G 1/98 Transgenic plant/NOVARTIS II , Official Journal EPO, 3/2000, at p.111.

[5] G 2/07 *Broccoli/Plant Bioscience* OJ EPO 2012, 130 and G 1/08 *Tomatoes/State of Israel* OJ EPO 2012, 130, 206

[6] Zimmer F.J.., & Grammel M., *Plant Patents in Europe*, Biotechnology Law Report. August 2015, 34(4): 121-131 (121). doi:10.1089/blr.2015.29006.fjz.

degrees[7]. Provided that member states guarantee the protection of plant varieties, either by patents or by a sui generis system or by a combination of the two, Article 27(3)(b) of the TRIPS agreement[8] explicitly allows member states to exclude plants from patentability and essentially biological processes for the production of plants. Hence some South American countries, China and the Indian Patent Act[9] take a very restrictive approach,. These countries exclude certain biotechnological subject matter, and especially plant-related inventions, from patentability.[10] In contrast, the US patent act is (still) far more permissive and includes no explicit statutory exemption of plant-related inventions. These may be protected by utility patents if all other patentability requirements are met. Not only claims directed to plants *as such*, but also plant parts, such as seeds and seedlings, and methods for the production of plants can principally be protected. This approach is *inter alia* based on the US Supreme Court decided in *Diamond v. Chakrabarty*[11], which already in 1980 held that genetically modified organisms constitute patent-eligible composition of matter in accordance with 35 U.S.C. § 101. Susequently, the Supeme Court explicitly confirmed in *J.E.M. Ag Supply v. Pioneer Hi-Bred*[12] the longstanding practice of the US Patent and Trademark Office to grant utility patents on plants.[13] The significance of these global controversies and international legislative differences, i.e. not only for the evolution of already existing applications, such as food-production and bio-fuels, but also for rapidly emerging fields of science with an enormous potential, such as gene-editing (CRISPR) and biomedical innovations, should therefore not be underestimated.

In the following, we will demonstrate how the EPO now appears to have chosen a middle-position, which differs substantially from some national legislations. In that context it should be noted that the procedural history of the Broccoli and Tomato saga is quite unique, since it was for the first time that the same consolidated cases were considered twice by the Enlarged Board. Moreover, the European legal framework, as well at the institutional and technical context of these cases is complex, which still leaves many questions open for debate. Accordingly, *section 1* of this paper will first provide a brief description of the European legal framework under the *European Patent Convention* (EPC)[14] and the *Biotech Directive*[15] and explain the institutional relationship between the relevant actors. This is followed by *section 2*, which delivers an account of the procedural history and the main arguments of the various parties to the case. *Section 3* will then briefly summarize the decisions. This provides the basis for *section 4*, where we analyse the legal effects and the practical implications of the decision. We will also explain why the affirmed patentability of product and product-by process claims resulting from conventional methods might

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[7] Janis, Mark D. "Patenting Plants: A Comparative Synthesis." In Patent Law in Global Perspective, by Okediji, Ruth L., and Margo A. Bagley, eds., edited by Ruth L. Okediji, and Margo A. Bagley. New York: Oxford University Press, 2014. Oxford Scholarship Online, 2014. doi: 10.1093/acprof:oso/9780199334278.003.0008, at I..

[8] AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS administered through the World Trade Organization, which went into force on January 01, 1995; available at: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 10 March 2015).

[9] Sec. 3 lit. h & j of The Indian Patent Act; http://www.ipindia.nic.in/IPActs_Rules/updated_Version/sections/ps3.html (excluding from patentability methods of agriculture or horticulture, plants in whole or parts thereof, and essentially biological processes for the production of plants).

[10] Zimmer F.J.., & Grammel M., *supra* n. 6 at 121-122 referring to Janis, Mark D., *supra* n. 7, at I.C.

[11] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[12] J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).

[13] See also Zimmer F.J.., & Grammel M., supra n. 6 at 121-122.

[14] Convention on the grant of European patents (EPC) of October 5, 1973 as revised by the Act revising art. 63 EPC of December 17, 1991 and the Act Revising the EPC of October, 29, 2000. The European Patent Convention currently has 38 contracting States, plus two so-called extension States (Bosnia and Herzegovina and Montenegro), available at: <www.epo.org/about-us/epo/member-states.html≥ (accessed May 7, 2015).

[15] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *Official Journal L 213, 30/07/1998.*

further effect the areas of GMOs and Synthetic Biology. How these results fit into the wider context of the ongoing European controversies over the patentability and commercialization of the aforementioned technological areas will be discussed in *section 5*. This will finally allow us to complete the paper with some concluding remarks in *section 6*.

1. The European Legal Framework

The European Patent Office (EPO)[16] is a supranational European organization that offers a centralized procedure for patent prosecution covering the signatory countries in accordance with the European Patent Convention (EPC). Once granted, a European patent is not a unitarian right. Rather it has in each of the contracting states for which it was granted, the same effects and is subject to the same conditions as a national patent granted by national patent offices.[17] The EBA is the highest instance of the European Patent Office, and its decisions are final and cannot be challenged before another judiciary.[18] The EBA decides on points of law referred to it by the Technical Boards of Appeal (TBA), gives opinions on points of law referred to it by the President of the EPO and also decides on petitions for review of decisions by the Boards of Appeal at the request of interested parties.[19] However, it should be noted that national courts (and/or the future European Unified patent court) retain exclusive jurisdiction concerning validity and infringement after a European patent has been granted - except during the 9-month opposition period, which can only relate to validity. National courts are not bound by the EPO Boards of Appeal decisions, but will take these into consideration and will tend to find the arguments of the EPO boards persuasive. Likewise the Court of Justice of the European Union (CJEU), which has competences to harmonise the uniform interpretation of EU legislation,[20] is not bound by the EBA jurisprudence.

On its turn, the Boards of Appeal may take into consideration decisions of national patent offices, national courts and the jurisprudence of the CJEU, but formally are not required to do so.[21] In fact, strictly speaking and in formal terms, the Boards of appeal of the EPO, are only bound to ensuring compliance with the norms of the EPC treaty understood as an independent and autonomous legal system for the grant of patents in Europe.[22]

The European Patent Convention contains three statutory exceptions to patentability contained in Article 53 EPC. Such subject-matter is considered to fulfil all patentability criteria, but is nevertheless excluded due to diverse public policy reasons. The "Broccoli" and "Tomato" cases concern the interpretation of the exception from patentability prescribed in Article 53 (b) EPC, which provides that European patents shall not be granted in respect of:

> "plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof".

[16] Art. 4 (1) EPC
[17] Art 4(3); Art 2(2); EPC and Art. 63 EPC.
[18] Art 112 (2) EPC. However, it should be noted that national courts (and/or the future European Unified Patents courts) have exclusive jurisdition concerning validity and infringement after a European patent has been granted (except during the 9-month opposition period, which can only relate to validity). National courts are not bound by the EPO Boards of Appeal decisions. However, national courts will tend to find the arguments of the EPO boards persuasive.
[19] Art. 22 and Art. 112 (a) EPC.
[20] Art. 19 Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union 2012/C 326/01 *Official Journal C 326 , 26/10/2012 P. 1 – 390*
[21] G 5/83 OJ EPO 1985, 64; T 154/04 OJ EPO 2008, 46.
[22] Art. 23 (3) EPC

The subject is further addressed in Rules 26 and 27 of the Implementing Regulations, which were adopted by decision of the Administrative Council[23] in order to implement the EU *Biotech Directive.* The Implementing Regulations are by statute considered as being integral parts of the EPC.[24] Rule 26 defines 'plant variety'; 'essential biological process' and 'microbiological process', as follows:

> (1) – (3) […]
> (4) "Plant variety" means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:
> (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
> (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
> (c) considered as a unit with regard to its suitability for being propagated unchanged.
> (5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
> (6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material."

At the EU level, the above mentioned *Biotech Directive* had been enacted in order to harmonize national legislation concerning the patentability of biotechnological inventions. In its Article 4 the Biotech Directive, which had to be implemented by the EU member states into their national legislations, establishes that plants varieties shall not be patentable, further elaborating that '*Inventions which concern plants [...] shall be patentable if the technical feasibility of the invention is not confined to a particular plant [...] variety.*

Essentially biological processes for the production of plants also shall not be patentable, '[…]*without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process."*[25] Article 2 of the Biotech Directive defines 'biological material' as "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*";[26] while 'microbiological process'' is defined as "*any process involving or performed upon or resulting in microbiological material*".[27]

A process is essential biological "*if it consists entirely of natural phenomena such as crossing or selection*",[28] and 'plant variety' is defined by reference to Article 5 of the Plant Variety Rights Regulation[29] where it is described as a "*plant grouping within a single botanical taxon of the lowest known rank*"[30]

All member states of the European Union (EU) are also signatory parties to the EPC. The EPC, however, is an international treaty and the EPO an European international organization but not an EU institution. Despite the lack of institutional link and formal obligation to do so, the provisions of the Biotechnology Directive have been taken into consideration by the EPO in the

[23] Decision of the Administrative Council of 16.06.1999, which entered into force on 01.09.1999 (OJ 1999, 437). Regarding the functions and competences of the Administrative Council *cf.* Art. 33 (1) (b) EPC.
[24] Art 164 (1) EPC.
[25] Art 4 Biotech Directive.
[26] Art. 2 (1) (a) Biotech Directive
[27] Art. 2 (1) (b) Biotech Directive
[28] Art. 2 (2) Biotech Directive
[29] Art 2 (3) Biotech
[30] Art. 5 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (Plant variety rights regulation).

formulation of the current Implementing Regulations,[31] which guide the application of Article 53 (b) EPC, namely by mirroring its content in Rules 26 and 27 (b) and (c) and establishing its relevance as a supplementary means of interpretation.[32] This explains also why the EBA refers to the provisions of the Biotech Directive in its decision.[33]

As a matter of institutional background, it should further be mentioned that the Court of Justice of the European Union (CJEU), who has the final word in interpreting the stipulations of the Biotech Directive, has not been called upon to pronounce itself over the interpretation of article 2 and 4 of the Biotech Directive. However, should such occasion arise, the jurisprudence set at the EPO Boards of Appeal would not bind the CJEU by precedent, nor in anyway limit the EU courts margin of appreciation. In fact, considering a previous decision on exceptions to patentability it is likely that divergence with the EBA may occur.[34]

Finally, it should be noted that only EU members-states national courts and tribunals may submit referrals to the CJEU, e.g. under the so-called preliminary ruling procedure in Article 267 TFEU[35]. The EPO Boards of Appeal, however, are not formally bound to comply with EU law and jurisprudence, nor does it have an institutional framework that would allow submitting matters of interpretation of the Biotech Directive to the CJEU's appreciation.[36] However, despite the formalities imposed by this institutional framework, as a matter of policy, the EPO has shown willingness to include the CJEU jurisprudence in its examination practice.[37]

Against this background, the following section will now first describe the procedural history of the Broccoli" and "Tomato" cases, before we will turn to the decision and its impact.

2. Procedural history

The debate concerning the interpretation of Article 53 (b) EPC in regards to the patentability of plants and plant related inventions has evolved mostly around the concepts of plant variety and essentially biological processes for the production of plants; it has been the subject of several decisions and two consolidated referrals to the EBA.

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[31] Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of 15 October 2014 (Implementing Regulations)

[32] Rule 26 (1) Implementing Regulations.

[33] G 2/12, Reasons at VII, point 4

[34] C-34/10, Oliver Brüstle v Greenpeace eV, Judgment of the Court (Grand Chamber) of 18 October 2011 ECLI:EU:C:2010:402. See Timo Minssen and Ana Nordberg, *The Evolution of the CJEU's Case Law on Stem Cell Patents: Context, Outcome and Implications of Case C-364/13 International Stem Cell Corporation*. (March 11, 2015). Available at SSRN: <http://ssrn.com/abstract=2576807> or <http://dx.doi.org/10.2139/ssrn.2576807> .

[35] Treaty on European Union and the Treaty on the Functioning of the European Union, Official Journal C 326 , 26/10/2012 P. 0001 – 0390.

[36] See T 276/99 OJ EPO and G 2/06 OJ EPO 2006, 306. In T 276/99 the Boards noted that, prima facie, as the EPO boards of appeal were not a court or tribunal of an EU Member State, they did not have the status to refer a question to the CJEU. In G 2/06 the appellant had sought a referral of questions to the ECJ on the argument that since the implementing regulations repeat the wording of the Directive, in such case the EBA is interpreting European Union law and should refer the question of interpretation to the ECJ. The request for a preliminary ruling by the ECJEU was rejected as inadmissible under the argument that neither the EPC nor the Implementing Regulations contain any provision allowing for a referral of questions of law to the CJEU.

[37] After the Brüstle decision the EPO amended its guidelines for examination in conformity with the CJEU decision of the patentability of hESC's. See Minssen and Nordberg, supra n. 34 (2015).

2.1 Consolidated cases Broccoli I & Tomato I

The case originates in two patents granted by the EPO on 26 November 2003. Patent EP1211926 (the 'Tomato patent') granted to the *Ministry of Agriculture of Israel* was opposed by *Unilever N.V.*. While patent EP1069819 (the 'Broccoli patent') was granted to *Plant Bioscience* and opposed by *Syngenta Participations AG* and *Groupe Limagrain Holding*, two agricultural biotech companies. The decisions of the respective Technical Boards of Appeal (TBA) were object to referral to the EBA. The procedures were consolidated resulting in decisions G 2/07 ('Broccoli I') and G 1/08 ('Tomato I)'.[38]

In cases 'Broccoli I' & 'Tomato I' the EBA was confronted with two processes for producing plants using conventional breeding techniques, i.e. techniques which could not be regarded as genetic engineering.[39] In the 'Broccoli patent' the invented process consisted of a non-microbiological process for the production of plants, containing the steps of crossing and selecting plants, plus an additional feature of a technical nature consisting of checking for molecular markers in the broccoli produced in order to guide the crossing and selecting process. While the 'Tomato patent' concerned a method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising mainly steps of conventional breeding techniques of selection and crossing, plus the additional steps of allowing the tomatoes to remain on the vine past the point of normal ripening, and visual screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.[40]

The consolidated decision of the EBA attempts to determine the meaning of "essentially biological" in the context of "essentially biological processes for the production of plants" within Article 53 EPC and Rule 26(5) EPC.

On May 22, 2007, in the opposition proceedings concerning the 'Broccoli I' case, the Technical Board of Appeal 3.3.04 referred the following questions to the EBA:

> "1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
> 2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?"[41]

Almost a year later, in opposition proceedings concerning the 'Tomato I' case, the same Technical Board of Appeal, by interlocutory decision T 1242/06 dated 4 April 2008, referred another set of identical questions to the EBA, adding the following:

> "1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
> 2. If question 1 is answered in the negative, […] [text identical to Q.1 in 'Broccoli I']
> 3. If question 2 is answered in the negative, […] " [42] [text identical to Q.2 in 'Broccoli I']

[38] G 2/07 Broccoli/Plant Bioscience OJ EPO 2012, 130 and G 1/08 Tomatoes/State of Israel OJ EPO 2012, 130, 206
[39] G 2/07, Summary of facts and submissions at, I point 2.
[40] G 1/08, Summary of facts and submissions at II point 2.
[41] Interlocutory decision T 83/05, dated 22 May 2007.
[42] Interlocutory decision T 1242/06, dated 4 April 2008

By decision of 21 April 2008 the EBA decided to consider the points of law referred by the TBA 3.3.04 in case T 83/05 (G 2/07 'Broccoli I') and in case T 1242/06 (G 1/08 'Tomato I') in consolidated proceedings.[43]

The questions at issue had also been the object of previous decisions by the EPO TBA's. Namely in T 320/87[44] where the TBA toke the view that whether or not a (non- microbiological) process is to be considered as "essentially biological" had to be decided on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved, and that the need for human intervention alone is not sufficient criterion for not being considered "essentially biological".[45] While later on T 356/93, the TBA examined the concept of microbiological processes and found that a process for the production of plants comprising an essential technical step, which has a decisive impact on the desired final result, does not fall under the exception to patentability under Article 53 (b) EPC.[46]

In this first set of referrals the EBA elaborated on the non-patentable concept of 'essentially biological process' identifying it with "*A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plant*".[47] Further adding, in accordance with T 320/87[48] that not just any kind of human intervention can suffice to elude the application of Article 53 (b) EPC. Stating that the patentability exception cannot be circumvented, merely by adding "*a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.*"[49] According to the EBA, a crossing and selecting process can be patentable if it contains an additional step of technical nature which by itself introduces or modifies a trait in the plant genome. This technical step must be so "*that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing*".[50] Concerning the valid criteria for determining whether a process is, or not, excluded from patentability as being "essentially biological", the EBA clarified that it is irrelevant "*whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.*"[51] Here the EBA diverged from the approach followed in T 320/87, and considered that any approach that relies on criteria determined by reference to the state of art is flawed, because it confuses considerations relevant for patentability with those relevant for assessing the patentability requirements, namely, novelty and inventive step.[52]

While considering the interpretation of *Rule 26(5) EPC,* the EBA found that a literal reading of the rule resulted ambiguous, if not contradictory.[53] The reasoning was that Rule 26 (5) states on the one hand that only processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants, while on the other hand also states that crossing and selection are given as examples of natural phenomena, and yet the systematic crossing and selection carried out in plant breeding are not natural phenomena (in the sense of spontaneously

[43] G 2/07 Broccoli/Plant Bioscience OJ EPO 2012, 130 and G 1/08 Tomatoes/State of Israel OJ EPO 2012, 130, 206.
[44] T 320/87 Hybrid plants/Lubrizol OJ EPO 1990, 112.
[45] T 320/87, Reasons at point 6.
[46] T 356/93 Plant cells/Plant Genetic Systems OJ EPO, 1995, 545, Reasons at point 40.1.
[47] Consolidated cases G 2/07 and G 1/08, Order answer to question 1
[48] T 320/87 Hybrid plants/Lubrizol OJ EPO 1990, 112
[49] Consolidated cases G 2/07 and G 1/08, Order answer to question 2
[50] Consolidated cases G 2/07 and G 1/08, Order answer to question 3
[51] Consolidated cases G 2/07 and G 1/08, Order answer to question 4.
[52] Consolidated cases G 2/07 and G 1/08, Reasons at point 6.4.1.
[53] Consolidated cases G 2/07 and G 1/08, Reasons at point 4.5.

occurring in nature) but measures implemented by means of human intervention.[54] For this reason the EBA examined the text of the Biotech Directive, and its legal history searching for clarification, concluding that this interpretative element did not provided the needed answers.[55] It also found that, since Rule 26(5) did not provide any useful guidance on the subject, the term "essentially biological process for the production of plants" should be interpreted on its own authority and that this was a task within the scope of the EBA jurisdictional authority.[56] The EBA turned then to the preparatory works of the EPC, concluding that the legislator intended to exclude from patentability the types of plant breeding processes which were at that time the conventional methods for the breeding of plant varieties, including those based on the sexual crossing of plants (i.e. of their whole genomes) and on the subsequent selection of the plants having the desired trait(s).[57] It also concluded that the choice of the word "essentially" was deliberate, reflecting a legislative intent to prevent the circumvention of the exception by mere use of a technical device in the breading process.[58] This justifying the answer provided, whereas the presence in a claim of one feature which could be characterised as biological does not necessarily result in the claimed process as a whole being excluded from patentability under Article 53(b) EPC, except where the process includes sexual crossing and selection. This meant that, in practice following this decision it has become nearly impossible to obtain patents concerning process claims containing crossing and/or selection steps, even where such are subsequent steps to a process initiated as 'non-biological', still the process may be considered essentially biological. Consequently, product claims have come to be seen by prospective patentees as a better option.

2.2 The 'Broccoli II' & 'Tomato II' referrals

After the issuance of 'Broccoli I' & 'Tomato I', both Patentees reacted by deleting the process claims. The remaining claims, in both patents relate to product and product and product-by-process claims. These amendments led to the second referrals, known as the consolidated cases G 2/12 'Tomato II' and G 2/13 'Broccoli II', and concern the question of determining whether the patentability exception in Article 53 (b) EPC extends or not to products of non-patentable methods. Such issues had not been addressed in the previous 'Broccoli I' & 'Tomato I' referrals and were thus left unsolved.

In the 'Tomato II' case the opponent reacted to the amended claims arguing that allowing claims to plants obtained by an essentially biological process would undermine the rationale supporting the EBA decision in 'Broccoli I' & 'Tomato I' and that it should not be acceptable to circumvent the patentability exception merely by changing claim format. The TBA justified the referral in 'Tomato II' by the fact that the patentee had restricted the claims to mere product claims that were not considered in the first referral. The claims were directed to dehydrated tomato fruits, and as such not considered a plant variety, but rather plant parts capable of producing entire plants.[59] However, the TBA questioned itself whether patenting such subject-matter would not render the patent exception completely ineffective, and thus defeating the legislative purpose.[60] The TBA also considered that such legal construction would allow patentees to indirectly obtain patent protection over excluded methods as the product claims would involve "*a broad protection which*

[54] ibid
[55] Consolidated cases G 2/07 and G 1/08, Reasons at point 4.8.3
[56] Consolidated cases G 2/07 and G 1/08, Reasons at point 5.
[57] Consolidated cases G 2/07 and G 1/08, Reasons at point 6.4.2.3
[58] ibid
[59] Interlocutory decision T 1242/06 dated 31 May 2012 OJ EPO 2013, 42, Reasons at points 33 to 39.
[60] Interlocutory decision T 1242/06 dated 31 May 2012 OJ EPO 2013, 42, Reasons at point 40.

encompasses that which would have been provided by an excluded process claim."[61] Having this in consideration and also the general interest of the questions for other pending applications, the TBA considered that a decision of the EBA was necessary and by interlocutory decision T 1242/06 dated May 31, 2012[62] the TBA referred the following questions to the EBA:

> "1. Can the exclusion of essentially biological processes for the production of plants in Article 53 (b) EPC have a negative effect on the allowability of a product claim directed to plants or plants material such as fruit?
> 2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filling date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?
> 3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53 (b) EPC?"

Around a year later, by interlocutory decision T 83/05 dated July 8, 2013[63] the TBA issued a second referral to the EBA (the 'Broccoli II' case). Questions 1, 2 (b) and 3 are identical to the 'Tomato II' referral. Questions 2 (a) and 4 consisting of further specifications of questions 2 and 3, read as follows:

> "2. In particular
> (a) Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants?"
> […]
> 4. If a claim directed to plants or plants material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53 (b) EPC, is it possible to waive the protection for such generation by "disclaiming" the excluded process?"

Concerning the reasons justifying the referral, the TBA refers to the respective reason of the 'Tomato II' case considering these to be essential to the appeal in case T 83/05. It also explained the option to refer modified questions (questions 2(a) and 4). Instead of simply stay the proceedings pending the answers of the referral in case G 2/12 'Tomato II',[64] the TBA considered that referring modified questions would allow for an answer encompassing the merits of the questions of law relevant to both cases.[65] The 'Broccoli II' case, although similar, differs in relation to the 'Tomato II' case insofar as the claims in the first are directed to plants and plants parts, whereas the 'Tomato II' *product claims* refer to fruits. Furthermore, the 'Broccoli' claims are constructed in the form of *product-by-process* claims, whereas the first auxiliary request contains an attempt to disclaim the excluded process. In the view of the TBA, these material divergences justified the need to specifically refer such issues to the EBA.[66]

2.3 Main arguments and 2nd case consolidation

Once again the EBA consolidated the two referrals in a single procedure and invited comments from the patent proprietors, from the opponents of the Broccoli case and from the

[61] Interlocutory decision T 1242/06 dated 31 May 2012 OJ EPO 2013, 42, Reasons at point 37.
[62] Interlocutory decision T 1242/06 dated 31 May 2012 OJ EPO 2013, 42, Order.
[63] Interlocutory decision T 83/05 dated 8 July 2013 OJEPO 2014, A39.
[64] Interlocutory decision T 83/05 dated 8 July 2013 OJEPO 2014, A39, Reasons at points 13 to 20.
[65] Interlocutory decision T 83/05 dated 8 July 2013 OJEPO 2014, A39, Reasons at points 21 to 22
[66] Id.

President of the EPO. The case raised considerable public interest and a considerable number of amici curia briefs were submitted.

The State of Israel, proprietor of the 'Tomato' patent, argued that the referral should be deemed inadmissible because the criteria of Article 112 (1) (a) EPC were not fulfilled[67], arguing that the EBA in G 1/98 'Transgenic Plant II'[68] already had concluded that only product claims directed to plant varieties are excluded from patentability under Article 53 (b) EPC.[69] Further adding that if the referral was to be considered admissible then decisions G 2/07 'Broccoli I' and G 1/08 'Tomato I' should be reviewed in order to exclude only those processes which result directly in a plant variety.[70] The State of Israel argued that rules of interpretation imply a narrow interpretation, and concluded that accordingly the first and third referred questions should be answered in the negative and the second in the affirmative.[71]

The proprietor of the 'Broccoli' patent - Plant Bioscience Limited - stated that the first question of the referral should be answered in the negative and therefor the remaining questions did not required an answer. Alternatively, the subsequent questions should be answered in favour of the allowability of a product claim or product-by-process claim as defined in the referral (second and third questions) or in favour of the allowability of "disclaiming" the process steps in the product claim that infringed the process exclusion in Article 53 (b) EPC (fourth question).[72] In similarity to the 'Tomato' patent owner, it was further argued that G 2/07 'Broccoli I' and G 1/08 'Tomato I' should be reviewed since the decisions originated a further referral. Plant Bioscience also sustained that exclusions should be constructed narrowly and that the exclusion should not be interpreted as extending to product claims which in the patentee's opinion are clearly distinguished from process claims in Article 53(b) EPC.[73]

The 'Tomato' patent opponent – Unilever - withdrew its appeal by its letter dated 28 June 2012 and in did not filed any submissions during the proceedings before the EBA, nor attended the oral proceedings.[74] On their turn, the two 'Broccoli' opponents submitted that questions 1, 3 and 4 should be answered in the negative, while question 2 should be in principle answered in the affirmative.[75] Syngenta Participations AG argued that the EBA decisions G 2/07 'Broccoli I' and G 1/08 'Tomato I' had already expanded the scope of the process exclusion to processes which as a whole have a technical character, this conclusion, being in conflict with Rule 27(b) EPC and the ordinary meaning of the term "essentially biological processes for the production of plants". Further adding that to exclude plants which are obtainable by an essentially biological process would result in nothing being patentable in the plant area.[76] Groupe Limagrain Holding, the second opponent to the 'Broccoli patent', argued in favour of the allowability of a plant product claim independent of the process implemented for making that product, even if the process was an essentially biological

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[67] Article 112 (1) (a) reads as follows: 1. "*In order to ensure uniform application of the law, or if a point of law of fundamental importance arises: (a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes. If the Board of Appeal rejects the request, it shall give the reasons in its final decision;*"

[68] G 1/98 '*Transgenic Plant/Novartis*' OJ EPO 2000, 111, available at: <http://documents.epo.org/projects/babylon/eponet.nsf/0/4831A04A31133EA6C12572C8006DFE59/$File/g980001.pdf > (accessed 10 May 2015)

[69] Consolidated cases G 2/12 and G 2/13: G2/13, Submissions of the parties at V point 1.1 .

[70] Id., at V point1.2.

[71] Id., atV points1.3 to 1.5.

[72] Id,, at V point 2.1.

[73] Id., at V points 2.2 to 2.7

[74] Id., at V point 3.

[75] Id., at V point 4.1 (a) and.4.2 (a).

[76] Id. , at V points 4.1 (d) and (e)

process. Accordingly the issue of disclaimers would not be necessary.[77] It further suggested that the claim should not confer protection on the use of the patented product to generate new, different plants which were outside the scope of the patent. In order to ensure this, measures should be implemented, for example in the form of a breeder's exemption in national law, or a waiver of protection in the form of a statement in the patent specification.[78]

The President of the EPO concluded that Article 53(b) EPC did not have a negative effect on the allowability of product claims to plants., also commenting that there is no indication, neither in the wording, nor preparatory works, supporting that the exclusion of essentially biological processes should be extended to products, further stating that any extension of an exclusion from patentability in this respect would be a matter for the legislator to decide.[79]

As mentioned these cases attracted a lot of attention in the patent community and society in general and, as a result, a considerable number of amici curiae briefs were submitted. These were filed by professional representatives, patent attorneys' associations, interest groups, farmers' associations, plant breeders, plant breeders' associations, seed producing associations and firms, scientists, politicians, and even private persons.[80] The contributes offered a wide range of opinions that can be grouped in three lines of reasoning: (1) several submissions concluded that the non-patentability of "essentially biological processes for the production of plants" did not imply a negative impact on the patentability of plants, plant material such as fruits, or plant parts;[81] (2) Others argued that claims directed at products derived from essentially biological processes were excluded from patenting under Article 53(b) EPC, as it was understood by the decisions of the Enlarged Board in cases G 2/07 'Broccoli I' and G 1/08 'Tomato I' as well as Article 4 Biotech Directive. Such views were grounded on arguments similar to those submitted by the parties to the proceedings and the EPO President, but also on scientific and economic aspects;[82] (3) the last group of amici curiae briefs expressed a number of general objections against patenting this type of technologies. Their objections were essentially based upon ethical, economic and social concerns related to the patenting of plants (and animals) in general and in particular of plants produced by conventional plant breeding methods.[83]

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[77] Id., at V point 4.2 (d)

[78] Id., para V.4.2 (e).

[79] Id., the President of the EPO submissions VI, point 1.1 to point 1.7 and ppoints VI.2.1 and VI.2.2.

[80] Id., the amici curiae submissions at VII point1.

[81] Id. , the amici curiae submissions at VII point2. See for example The Charted Institute of Patent Attorneys (CIPA), Amicus Curiae brief in G 2/12, received December4, 2012 stating that "*the patentability of a product is in principle independent of the process by which is made*"; also in International Federation of Intellectual Property Attorneys (FICPI), Amicus Curiae brief in G 2/12, November 28,2012, the FICPI offers a similar understanding and argues for a narrow interpretation of the exception; while in Union of European Practitioners in Intellectual Property, Amicus Curiae brief in G 2/13, November 28, 2013, at para 57-60, it is added that extension of the exception to products is not justified, and that Plant breeders right do not provided for adequate protection due to the existence of a breeders exemption, which allows breeders to use the patent variety for the production of new plant varieties, as long as these new plant varieties are not essentially derived from the protected variety; on its turn and in similarity in the International Association for the Protection of Intellectual Property (AIPPI), Amicus Curiae brief in G 2/13, November 29, 2013, the AIPPI argues that Questions 1 and 3 should be answered in the negative, Questions 2a and 2b in the affirmative, while question 4 would not require an answer. It is stated that the patentability of a product is independent of the patentability of the process by which it is made and that "*this is settled law and should not be disturbed*". To decide otherwise, in the AIPPI opinion, would imply to override many established patent law principles.

[82] Id., the amici curiae submissions at VII points.3 and 4. An example would be the submission of the European Seed Association, which argued the necessity to extend the patentability exclusion to products, in order to avoid the exception to become meaningless. See European Seed Association, Amicus Curiae brief in G 2/13, September 26, 2014.

[83] Id., the amici curiae submissions at VII point 5 See for all European Parliament Amicus Curiae brief in G 2/12, November 28, 2012, consisting of a Motion for a resolution on the patenting of essential biological processes (2012/2623 (RSP)), at point 4, in which the EU parliament "*calls on the EPO also to exclude from patenting products*

3. The Decision(s)

First of all, the EBA rejected the *State of Israel* arguments for inadmissibility of the 'Tomato II' referral, appeals, concluding that in both cases an answer to at least some of the referred questions was necessary. The Board found that G 1/98 'Transgenic Plant' had not commented on the extension of the exclusion to essentially biological processes to products and that G 1/98 'Transgenic Plant' only concerned the plant variety exclusion. It also stated that these referred questions have relevance beyond the cases in which they had arisen. In the view of the EBA their importance extends to similar cases and would therefore serve the uniform application of the law.[84] Consequently, both referrals were deemed admissible.[85]

Having observed that the referring questions do not relate to the plant variety exclusion or to the patentability of essentially biological processes, the Board held next that there was no need for a further review of either G 1/98 'Transgenic Plant II', G 2/07 'Broccoli I'or G 1/08 'Tomato I'.[86]

Subsequently, the board turned to an examination of the interpretative meaning of the exclusions codified in Article 53(b) EPC in order to determine whether a narrow or a broad interpretation should be given to the language. First, the EBA noticed that

> "there is no general notion of an obligatorily restrictive construction of exceptions to patentability, for example, such as that adopted by the Court of Justice of the European Union (CJEU) when insisting on a narrow interpretation of exceptions to or derogations from fundamental EC Treaty principles embodied in the four freedoms."[87]

However, then the EBA went on in stating that "*such a narrow interpretation might well result from applying the general principles of interpretation to a specific provision with regard to specific legal and factual circumstances.*"[88] After a more comprehensive examination and application of the traditional methods and rules of legal interpretation considering *grammatical*, *systematic*, *teleological*, and *historical* interpretative methods as well as *subsequent agreements and practice*[89], the EBA decided indeed to interpret the Article 53 (b) EPC narrowly.

This narrow interpretation was mainly based on *legal-systematic* considerations and was held to be derivable from (1) the systematic and contextual positioning of Article 53 (b) EPC among exceptions to patentability within Chapter I of Part II of the EPC, and by (2) the identification of an analogy to rule 27 (b) EPC, which provides that *biotechnological* inventions relating to plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety.[90]

The usefulness of a *teleological* interpretation under the "ratio of legis", was rejected by the EBA[91] based on the observations made by the EBA in G 2/07 'Broccoli I' and G 1/08 'Tomato I', where it was stated:

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derived from conventional breeding methods and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding".

[84] Id., Reasons at I. para 5.

[85] Id., Reasons at I. para 2-8.

[86] Id. Reasons at III.

[87] Id. Reasons VI (2) (citing the ECJ (now CJEU) judgment of 21 June 1974 in C 2-74, Jean Reyners v. Belgian State, ECJ 1974, 631)..

[88] Id.

[89] Id.

[90] Id. Reasons at VII, point 2.

[91] Id. Reasons at VII, point 3.

> "However, since the respective legislative purposes behind the sub-items in Article 53 EPC and even those behind the alternatives of Article 53(b) EPC are quite different, the systematic context of the exclusion of essentially biological processes from patentability, namely its place in Article 53(b) EPC, does not as such indicate what the purpose of the provision is".[92]

The EBA found this conclusion still to be valid and accordingly held the object and purpose of the exclusion under Article 53(b) EPC not to be sufficiently obvious to answer the question whether or not the clause is to be construed in a narrow or broad way. *Subsequent agreement or practice*, and *historical interpretation*, both internationally acknowledged as methods of interpreting provisions of treaties, such as the EPC, and codified in by Articles 31 and 32 of the Vienna Convention on the Law of Treaties[93], were also not regarded as being feasible in interpreting the scope of the exclusion.[94]

In following the above described *systematic* approach, the Enlarged Board could *not* find any sufficient indication or evidence in the EPC that the exclusion of "essentially biological processes for the production of plants" in Article 53(b) EPC is to be interpreted broadly such that it extends beyond the excluded processes to products defined or obtained by such processes.[95]

Although not addressed by the parties, the Board then considered an issue that was raised in the various *amicus curiae briefs.* That is whether the fundamental legal impact of this understanding of Article 53(b) EPC requires secondary considerations[96] and the application of *dynamic interpretations*, to broaden of the scope of the process exclusion if, for example, the interpretation would be at odds with the legislator's intention.[97] Yet, the EBA did not consider this to be the case. It pointed out that the concept of dynamic interpretation does not require revising the result of the interpretation established by applying traditional rules of construction and that an extension of the restriction was thus not necessary.[98] In that regard, the EBA observed that extending the exclusion to cover plants or plant materials would result in inconsistency within the EPC, since such products are generally eligible for patent protection (other than plant varieties).[99] The EBA also stressed in particular that the chosen narrow interpretation of the exclusion did not lead to an erosion of the exception, so that "*the legislator's intentions could be frustrated by the choice of the claim category and by "skilful" claim drafting*", since the process was still excluded from patentability and the product claim still must satisfy the other criteria for patentability (such as novelty and inventive step).[100]

Furthermore, and referring to its earlier decision in G 1/98 'Transgenic Plant II', the EBA emphasized that the EPC unmistakably provides for a clear distinction between, on the one hand, the question and aspects of patentability of a claimed subject-matter (Articles 52 to 57, 76, 83, 84 and 123 (EPC), and, on the other hand, the separate question of the scope of protection (Articles 64 (2) and 69 EPC) that is conferred by the claim.[101]. In that regard, the Board noted that although *product* or *product-by-process* claims may encompass and provide protection for not only the product but for the use of a product and production of the product, the relevant point of law that was

[92] G2/07 and G 1/08, *supra*, Reasons at point6.4.2.1.
[93] Vienna Convention of the Law of Treaties of May 1969.
[94] Consolidated cases G 2/12 and G 2/13, Reasons at VII, point 4.-5.
[95] Id. Reasons at VII, point 6 (First intermediate conclusion).
[96] Id. at VIII.
[97] Id. at VIII., point 1
[98] Id., VIII, point 2 (1)-(6).
[99] Id. VIII at point 2.
[100] Id.
[101] Id. Reasons at VIII point 2(6) (a) and in particular (b).

referred to the EBA in these cases is "*whether subject matter is excluded from patentability*, but *not the scope of protection conferred by such a claim*."[102]

The Board therefore concluded that the "essentially biological process" exclusion of Article 53(b) EPC does not prevent the patentability of claims directed to plants or plant material, such as a fruit or plant parts, provided that they do not claim an individual plant variety. Thus in the case of G 2/12 – 'Tomato II' - the Board answered the first and third referred questions in the negative and the third question in the affirmative, using a double negation. In summary, the EBA's decision therefore gave the following answers to the questions of law referred to it in G 2/12 'Tomato II':

1. The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit.
2. In particular, the fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.
3. In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC.[103]

In the case of G 2/13 – 'Broccoli II' the EBA's answers were essentially the same, but, in addition, clarified that the above conclusions equally apply to product-by-process claims. Thus, the *first* and *third* questions were once more answered in the negative and the *second* question was once more answered in the affirmative, using a double negation. Moreover, the Board considered that the fourth question of law - asking whether the problem could be resolved by a disclaimer - was not applicable and hence did not require an answer.[104]

4. Legal analysis & practical implications

'Tomato II' and 'Broccoli II' have made unmistakably clear that Article 53(b) EPC does not preclude the grant of compound claims directed to plant or plant material resulting from an process excluded *as such* under the same provision. Hence, if an invention relates to an "essentially biological process for the production of plants or animals", which is explicitly excluded *as such* under Article 53(b) EPC, the product resulting from such a process can still be patented, as long as the following criteria are met:

- the claimed plant or plant material meets further basic patentability requirements such as novelty (Article 54 EPC), inventive step (Article 56 EPC) or industrial application (Article 57 EPC),
- the application contains appropriate language to sufficiently define the claimed product, which may in certain situations be achieved by using product-by-process claim language, and
- the patent does not claim a plant variety as such, which are also excluded by Article 53(b).

In essence the decisions thus confirm that claims directed to novel and inventive plants obtained by methods which include breeding steps, as opposed to plant varieties, should in principle be allowable under the EPC, irrespective of whether claimed in a *product per se* or *product-by-process* format. Patent protection will only be categorically denied if the product is a "plant variety".

[102] Id. Reasons at VIII, point 2(6) (b).
[103] Id., operative part of the decision (Order of the Court).
[104] Id. operative part of the decision (Order of the Court).

However, only a claim to a single plant variety is excluded under Article 53 (b) EPC (first part of clause), which was not the case in either of the referred situations. In that regard it should be remembered that the EBA rejected the argument for a new review of decision G1/98 'Transgenic plant II'/[105]. Consequently the following finding by the EBA in G 1/98 still applies: "*A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), EPC even though it may embrace plant varieties.*"

The ultimate significance of G 2/12 'Tomato II' and G 2/13'Broccoli II' is accordingly that the EPO will continue to grant patents on plant inventions as it did before the last 'Tomato I' referral in 2011. This decision was not entirely surprising, since the President of the EPO commented on the referrals leading to G 2/12 and G 2/13 and came to essentially the same conclusion. This outcome is of course very positive news for patent applicants engaged in GMO's and innovative plant breeding. However, at least one stakeholder, the Berne Declaration and SWISSAID group, has stated that the decision favours giant agrochemical companies and will hinder innovation in the area of plant and animal selection from small plant breeders.[106] The sensitive and very multifaceted discussion over the wider impact of these decisions, however, falls outside the scope of the paper and will only briefly addressed in our discussion and concluding remarks.

An interesting additional aspect to the decision that should be carefully observed is that the outcome of the 'Tomato II' and 'Brocolli II' decisions stands in stark contrast to the national patent legislation of some major contracting states. In Germany or The Netherlands for example – two countries with a considerable industry conventionally active in the relevant fields - national patent legislation explicitly excludes products produced by essentially biological processes as well as the processes themselves. Accordingly the 'Tomato II' and 'Broccoli II' patents would not have been granted in these jurisdictions. This is also explicitly recognized in the EBA decision at VIII.2.6 (d) of the Reasons, where the EBA discusses national patentability exclusions of plants which are produced by an essentially biological process:

> Furthermore, the Enlarged Board takes note that those legislatures that are of the view that plant products obtained by essentially biological processes should not be patentable have chosen to amend their legislation in this respect, thereby deviating from the wording of Article 53 (b) EPC. Both in Germany and in the Netherlands legislation exists excluding product claims from patentability where the claimed products have been generated by an essentially biological process for the protection of plants (see § 2 a (1) No.1 German Patent Act of 1936, as last amended in 2013; Article 3 (1) (d) Dutch Patent Act of 1994, as last amended in 2014). No such amendments have been made in, for example, the United Kingdom (see Section 76A and Schedule A2 (1) (b) and (3) (f) UK Patents Act of 1977, as last amended in 2014), France (see Art. L. 611-19 CPI, Loi no 2004-1338 of 8 December 2004, I. 3), Austria (see §2 (2) Austrian Patent Law of 1970, as last amended in 2014) and Switzerland (see Article 2 (2) Swiss Patent Law of 1954, as last amended in 2012).[107]

This finding has *two* implications. *First* of all, the amendment of the German Patent Act of June 27, 2013, explicitly excluding product claims on plants and animals exclusively obtained by essentially biological processes *in addition to* the already excluded essentially biological processes, could indeed be interpreted has an indication that at least some legislators found that Article 53(b) EPC in its current wording does not unambiguously exclude *products* of essentially biological

[105] Decision of the Enlarged Board of Appeal dated 20 December 1999 in G 1/98 Transgenic plant/NOVARTIS II , OJ EPO 2000, 111.
[106] See Catherine Saez, *EPO Backs Patents On Conventional Plants: Broccoli, Tomato Cases Decided,* Intellectual Property Watch 01/04/2015, available at: <http://www.ip-watch.org/2015/04/01/epo-backs-patents-on-conventional-plants-broccoli-tomato-cases-decided/≥ (accessed 14 May 2015).
[107] Consolidated cases G 2/12 and G 2/13, Reasons at VIII.2.6 (e).

processes.[108] This would actually support the EPO's narrow interpretation of Article 53 (b) EPC.[109] Alternatively it could be argued that these amendments of the German and Dutch Patent Act "indicate that at least the German and Dutch legislator interpret the Biotech Directive accordingly".[110] This in turn raises the question of how the CJEU would interpret the Biotech Directive with respect to the exclusion of essentially biological processes under Article 4(1)(b) of the Biotech Directive.[111]

Second, while the disparities between the EPC and national laws continue to render the European patent application procedures rather complicated, 'Tomato II' and 'Broccoli II' provide unambiguous signals encouraging applicants who intend to obtain a patent for such plants to prosecute their patent applications at the European Patent Office. This is certainly significant from a practical perspective. Yet, it still remains to be seen how such patents will succeed during the national litigation phase.

This brings us to the emerging Unitary Patent system and another issue, which relates to the following statement made by the EBA in "Tomato II":

> "As pointed out by the referring Boards, by virtue of Article 64(2) EPC: (a) the protection conferred by a process claim extends to the products directly obtained by such process, (b) the protection conferred by a product claim comprises using as well as producing the product and *(c) the product claimed in terms of a product-by-process claim extends to products which are structurally identical to the claimed product but which are produced by a different method*."[112]

In particular point (c) in this statements indicates that the EBA interprets the scope of protection of a product-by-process claim in a very broad manner, which does not restrict the scope of protection of a product-by-process to merely products which are obtained by the process steps described in that claim. Some national civil courts in Europe which hear patent infringement cases, however, appear to have much narrower views on the scope of protection that is awarded to such claims.[113] The question is then what this might mean with regard to the emerging unitary Patent System under the rules of the so-called European Patent Package.[114] Some commentators have pointed out that:

> While the statement of the Enlarged Board is at best an *obiter dictum* and not binding for any national court, it might become relevant once the Unified Patent Court is operating in Europe. Namely, according to Article 24 (1) (c) of the Agreement on a Unified Patent Court, one source of law for procedures before that Court shall be the European Patent Convention. This source of law might well include the case law

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[108] Hanna Kompagne, EPO - A decision less green – but is it sweet yet?, EPLAW Patent Blog (13.04.2015), available at: http://www.eplawpatentblog.com/eplaw/2015/04/epo-a-decision-less-green-but-is-it-sweet-yet-.html (accessed 19 May 2015).

[109] This seems also to have been realized by the EBA, see: Consolidated cases G 2/12 and G 2/13, Reasons at VIII.2.6. (d).

[110] Franz-Josef Zimmer and Markus Grammel, *Plants Patents in Europe*, available at: http://www.grunecker.de/files/fz+hr._grammel_publikation_plant_patents_in_europe.pdf (accessed 30 July 2015).

[111] Id.

[112] Id, Reasons at VIII.2.6 (b) (emphasis added).

[113] For a much more detailed discussion, *see* e.g. Sven J.R. Bostyn, *Resolving the patentability of plants produced by an essentially biological process conundrum: Squaring the circle?* E.I.P.R. 2013, 35(7), 383-396.

[114] The EU "patent package" consists of the Agreement of 19 February 2013 on the Unified Patent Court (UPCA); Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection; and Council Regulation (EU) No. 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation requirement. *Cf.* Preliminary set of provisions for the Rules of Procedure ("Rules") of the Unified Patent Court, 17th draft Of 31 October 2014, available at: http://www.unified-patent-court.org/images/documents/UPC_Rules_of_Procedure_17th_Draft.pdf (last visit 17 March 2015).

> under the European Patent Convention, including the case law of the Boards of Appeal and especially of the EBA of the European Patent Office. As such, 'Tomato II' and 'Broccoli II' might become relevant in the future when product-by-process claims are litigated before the Unified Patent Court.[115]

Althought not directly relevant to the current case it should in that context perhaps also be mentioned that different interpretations of the scope of protection that should be referred to biologic inventions is nothing new in Europe. This can be best demonstrated by the debates surrounding patents on human DNA sequences. The somewhat ambivalent drafting of the Directive has resulted in diverging national interpretations and implementations of the Directive. In contrast to the EPO (see further below), or e.g. Sweden and the U.K.[116], some countries in the EU, such as Germany and France, have even introduced legislation that categorically limits the scope of product protection for certain types of (human) DNA sequences and – as far as France is concerned – even protein sequences. These rules oblige applicants to incorporate the specifically identified and disclosed industrial application of i.a. (human) DNA sequences into the patent *claims* and not only the patent *description*. By restricting the patent's scope of protection to the particular application that has been sufficiently disclosed, such legislation only grants purpose-bound product protection but no full product protection for certain DNA (and/or protein) sequences.[117]

In 2010, this practice appears to have found some support in the *Monsanto v. Cefetra* decision[118] of the Court of Justice of the European Union ("CJEU"). This seminal decision concerning genetically modified plants and seeds has given rise to its own interesting problems and unclear issues. Although the Court questioned the scope of protection conferred to genes, no principled analysis of the patent-eligibility of human genes patents and the full product protection issue could be found.[119] Hence, in Europe, the patent-eligibility of human genes still follows the statutory principle laid down in Article 5 (2) of the Biotech Directive[120]. But for how long?

Having touched upon genetically modified plants, a few words should finally be added concerning the combined significance of these two consolidated referals, which is more far-reaching and relevant for all plant-related inventions. 'Broccoli I'& 'Tomato I' had the impact of creating a higher threshold of technical intervention in order for novel and inventive processes relating to plant production to be able to avoid the qualification – "essentially biological process". As mentioned above, the EBA defined 'essentially biological process' as "*a non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the*

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[115] Christian Köster, *Additional lessons learned from Tomato II and Broccoli II*, available at http://www.dennemeyer.com/lessons-tomato-broccoli (accessed 10 May 2015).

[116] A detailed discussion of the troubled history of the Biotech Directive's national implementations is provided by T. Minssen, KliFoRe, Heft Nr. 3 und 4 (2008), *Es bleibet dabei: Eine schwedische Stellungnahme zur europäischen Debatte über den absoluten Erzeugnisschutz bei der DNA-Patentierung*, p. 93 ff., available at http://jura.ku.dk/ciir/ansatte/?pure=da/persons/381631 (last visit 10 April 2015).

[117] For a more thorough discussion of the different national implementations, *see* T. Minssen, *id.* , p. 93 ff.

[118] *See* Case C-428/08 *Monsanto Technology LLC v Cefetra BV* 6 July 2010 (Grand Chamber) [2010] ECR I-6765.

[119] Although the facts of the case did not concern human DNA and the decision focused mainly on article 9 of the Directive. Yet, the decision also contains general statements on the TRIPS agreement and further provisions of the Directive, such as Article 5. For further analysis and criticism of the judgment, cf. Michael A. Kock, *"Court of Justice of the European Union Limits Patents on DNA Sequences: Much Ado About Nothing or The Beginning of Erosion for Biotech Patents?"*, 11 BSLR 1, 3-12; Overwalle, G. van (2011). *"The CJEU Monsanto soybean decision and patent scope: As clear as mud*". International Review of Intellectual Property and Competition Law, 42(1), 1-3, and Kock.M.A.*"Purpose-bound protection for DNA sequences: in through the back door?"*, Journal of Intellectual Property Law & Practice 2010 5, 495-513.

[120] Article 5 (2) of the Biotech Directive states: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".

whole genomes of plants and of subsequently selecting plants".[121] It also added, that the patentability exception cannot be circumvented, merely by adding "*a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.*"[122] Accordingly, a crossing and selecting process can only be be patentable if it contains an additional step of technical nature which by itself introduces or modifies a trait in the plant genome and which is not the "*the result of the mixing of the genes of the plants chosen for sexual crossing*".[123]

From a functional prespective, it should be pointed out that the legal criteria encompasses both conventional crossing and selection methods and genetic engeneering, insofar as the process involves the sexual crossing of whole genomes or the recombination of whole genomes of plants.[124] Emerging technologies, such as synthetic biology, are mostly characterised by cross-disciplinarity and the use of a mixture of techniques, some of which may be considered to fall under the 'essentially biological' legal concept. In practice, it has thus become very unlikely for a patent to be granted in Europe containing process claims directed to crossing and/or selection steps, even where these are subsequent steps in a process involving a vast array of techniques.

In this sense the present decision in 'Broccoli II' and 'Tomato II', which allows product and product-by-process claims even if obtained by processes that may fall under the 'essentially biological' proviso has provided many new patent options for the entire plant science community.[125] However, national legislators have chosen a different approach and also on the EU level there is still a risk that the CJEU might decide otherwise. From a practical perspective this implies that patent applicants should continue to spend efforts in predominantely using classical product claims wherever possible and appropriate.

5. Discussion: The decisions within a wider context

Throughout this paper we have described and discussed complex patentability issues pertaining to the legal interpretation of the EPC, it's implementing rules and the Biotech Directive. It was also pointed out that the legal implications of this EBA ruling escape the boundaries of the specific case and Article 53 (b) EPC, both in theoretical and in practical implications for prospective patentees.

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[121] Consolidated cases G 2/07 and G 1/08, Order answer to question 1

[122] Consolidated cases G 2/07 and G 1/08, Order answer to question 2

[123] Consolidated cases G 2/07 and G 1/08, Order answer to question 3

[124] See also Hanna Kompagne, supra n. 108 (adding: "This broad interpretation has created a certain degree of uncertainty regarding the future of the European plant industry. In an amicus curiae brief the epi (for one) pointed out the possible effects of such an approach on genetically engineered plants: "Should the notion prevail that products of an excluded essentially biological process for the production of plants in the sense of G 2/07 are also not patentable, genetically engineered plants may also not be patentable under Article 53(b) EPC. Of particular concern are for instance mixed processes comprising both technical (i.e. non-biological) and biological steps. Presumably, there is no example of a transgenic plant that was marketed without having undergone at least one round of crossing and selection after the genetic engineering.

[125] Cf. Id. ("This leads us to another interesting issue: how to design research in a laboratory – and not only in botany labs. Genetically modified animals as disease models, for example, are widely used, but there is always room for improvement. It is thus perfectly possible to make a GM animal with multiple added traits, whereas the animal is not new or does not involve an inventive step per se, although the process leading to the animal contains new and inventive technical steps (and crossing of course). It is usually easier, safer, cheaper and more reasonable to cross two different GM animals, knowing or hoping that the offspring will have both desired features than to introduce both features into the same animal by technical means. However, scientists may be forced to make such animals without crossing, if they wish to obtain protection for their invention in Europe").

In that context, it should not be forgotten that this case cannot only be evaluated by legal reasoning. It also needs to be discussed within a much larger societal and political context in Europe surrounding the fierce debates over emerging scientific and technologic advances: The issue of GMO's and its implications for innovations pertaining to plant science research in emerging fields such as synthetic biology, but also for related fields of science with enormous potential, such as gene-editing technologies (CRISPR) and biomedical innovations.

In Europe, the adoption of a precautionary principle or approach concerning regulation of emerging technologies has created a paradoxical situation in plant science research and industry. On the one side European scientists are at the forefront of research concerning the creation of transgenic crop varieties engineered for resistance to specific diseases, enhanced nutritional properties and other desirable traits. On the other side, during the past 15 years only two GM crops have been approved for commercialization by the European Commission. (EC)[126] Monsanto's MON810 maize (resistant to a number of insect herbivores) is currently the only GM crop cultivated in the EU. The only other GM crop approval by the European Commission, BASF's "Amflora" GM potato, was annulled by the EU General Court in 2013.[127]

In 2006, a World Trade Organization dispute settlement Panel found that that the then European Communities (now EU) had applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, and ruled that, by applying this moratorium, the European Communities had acted inconsistently with its international obligations.[128]

Strong and constant public opinion opposition to GMO's has been the major driver behind such policy. Partly the lack of approvals can be explained by the fact that until recently every member state had to accept and enforce EC approvals of GMO's. In Case C-36/11[129] the CJEU clearly stated that has once the use and marketing of a GMO product has been authorized pursuant to Regulation 1829/2003 and has been listed in the common catalogue of varieties of agricultural plant species under Directive 2002/53/EC, national authorities may not impose additional requirements on the grounds of the protection of health or the environment, such as a national authorisation procedure. The limited competence of member states to restrict the cultivation of GMO crops in their territory, meant the creation of a *de facto* moratorium over approvals of GMO's, due to strong opposition of some member-states.[130] Recently the European Parliament agreed to allow individual states to restrict or ban the cultivation of crops containing GMOs on their own territory, despite them being approved for use by the European Commission.[131] Symptomatically, the legislation, originally tabled in 2010, was deadlocked for four years due to disagreement between pro- and anti-GMO member states, as well as ongoing controversies over the

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[126] Editorial 'Europe compromises on GM crops', Nature Plants 1, Article number: 14022 (2015) doi:10.1038/nplants.2014.22, Published online 08 January 2015, available at: http://www.nature.com/articles/nplants201422 (accessed 10 May 2015).

[127] Case T-240/10 Hungary v Commission, Judgment of the General Court (First Chamber, extended composition) of 13 December 2013. ECLI:EU:T:2013:645.

[128] World Trade Organisation Dispute Settlement Pannel, United States v European Communities, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, DISPUTE DS291, aAvailable at: <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm> (accessed 10 May 2015).

[129] Case C-36/11 Pioneer Hi Bred Italia Srl v Ministero delle Politiche agricole alimentari e forestali, Judgment of the Court (Fourth Chamber) of 6 September 2012, ECLI:EU:C:2012:534.

[130] Editorial 'Kicking the can' Nature biotechnology 33, 111 (2015) doi:10.1038/nbt.3148, Published online 06 February 2015, available at: <http://www.nature.com/nbt/journal/v33/n2/full/nbt.3148.html> (accessed 10 May 2015).

[131] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory OJ L 68, 13.3.2015, p. 1–8

Convention on Biological Diversity and the Nagoya Protocol.[132] At first sight, this new Directive would appear to be another setback for the Plant Science community, as it allows members states to impose restrictive measures. However, this may actually also open new possibilities, since it is hoped that the new legislation will facilitate the approval of GM crops and thus allow its cultivation and commercialization in member states with less restrictive views on the subject.

Negative public perception does not result only from the strong opposition to GMO's campaigned by different environmentalist organisations and political parties. Also farmers associations have joined the debate, opposing the patentability of plant related inventions as a matter of concern that such patents will foster market concentration, making farmers and other stakeholders of the food supply chain increasingly dependent on a small number of large international corporations. Consumer protection and consumers rights to information also form part of the flagship issues nourturing the public debate.[133] Thus, it is not surprising that the EBA's decision in the consolidated cases G 2/12 'Tomato II' and G 2/13 'Broccoli II' has generated reactions of alarm and calls for revision of EU Patent Law, among accusations to the EPO of favouring the arguments and interests of giant agrochemical companies. The decision has been criticised as offering a gateway to completely bypass the provisions of the Biotech Directive, the Berne Declaration and SWISSAID commented that over 7,500 patent applications on plants and 5,000 applications for animals have been filed at the EPO, 3,800 patents have been granted, 120 of which relate to conventional selection processes, while around 1,000 applications are pending.[134] It is thus, likely that such patents may continue to be object of opposition procedures at the EPO, as it is reasonable to predict that increasingly infringement/invalidation actions concerning national patents will surface in national courts[135] and eventually reach the CJEU.

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[132] Parliament backs GMO opt-out for EU member states, Press release - Environment − 13-01-2015, available at <http://www.europarl.europa.eu/news/en/news-room/content/20150109IPR06306/> ; Cf. Convention on Biological Diversity, 1760 UNTS 79; 31 ILM 8818 (1992); and Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to Convention on Biological Diversity, Nagoya, 29 October 2010, available at http://www.cbd.int/cop10/doc (accessed 10 March 2015). (accessed 10 May 2015).

[133] See for example the position of The international coalition of No Patents on Seeds! calling for a revision of European Patent Law to exclude breeding material, plants and animals and food derived thereof from patentability. According to their website, the coalition is supported by several hundred other organisations, including: Bionext (Netherlands), The Berne Declaration (Switzerland), GeneWatch (UK), Greenpeace, Misereor (Germany), Development Fund (Norway), No Patents on Life (Germany), Red de Semillas (Spain), Rete Semi Rurali (Italy), Reseau Semences Paysannes (France) and Swissaid (Switzerland). In <http://no-patents-on-seeds.org/> (accessed 10 May 2015).

[134] Christoph Then and Ruth Tippe 'European Patent Office at Crossroads: Report about Patents on Plants and Animals Granted in 2011', Coalition No Patents on Seeds, March 2012, available at: ttps://www.bernedeclaration.ch/news/european_patent_office_at_crossroads_report_about_patents_on_plants_and_animals_granted_in_2011/ (accessed 10 May 2015)

[135] An example can be found in the recent 'radish Netherlands case'. Taste of Natures developed a seedling of a radish being characterized by a high level of anthocyanin (antioxidant), protected by European patent EP 1 290 938 ("EP '938"), as validated in the Netherlands. The patent inter alia relates to methods for the production of the seedling. Although the final decision on the merits was eventually based on matters of lack of novelty, on 31 January 2012 the judge in summary injunction proceedings of the District Court of The Hague rejected Taste of Nature claim for infringement against Cresco, and considered the patent invalid in view of the exclusion of patentability under article 53(b) EPC. The court reasons that the method was unpatentable for being an essentially biological process, but also considers that a product directly obtained by using that method, would likely be unpatentable because a method claim also protects the product directly obtained using that method. Taste of Nature Holding B.V. v. Cresco Handels-B.V., proceedings on merits, District Court The Hague, The Netherlands, 8 May 2013, Case No. / Docket No. 416501 / KG ZA 12-452decision of District court of the Hague, decision of 8 of May Taste of Nature B.V. v. Cresto Handels B.V. Unofficial English translation available at: <http://www.eplawpatentblog.com/eplaw/2013/06/nl-taste-of-nature-cresco.html> (accessed 10 May 2015).

Although the EBA decision is favourable to patentees by applying a narrow understanding on the scope of the exception, an eventual referral to the CJEU may once again change the patentability landscape in Europe. The CJEU is not bound in any way by the decisions of the EBA and because it uses different interpretative methods and resorts to different sets of sources of law it may reach a different decision. In this respect, any legislative initiatives by the EU parliament in this area may influence the outcome of such an eventual referral.

It has also been reported that, from a regulatory perspective new techniques in plant breeding linked to contemporary genetics and genomics challenge the boundaries between GMOs and conventional breeding. It may be increasingly difficult to define whether the technologies used give rise to GMOs as defined by current EU legislation.[136]

Another source of concern for prospective patentees in Europe is the possibility of a spill over effect of the GMO's negative public perception into emerging scientific and technological fields, such as Synthetic Biology and genetic editing, because distinctions and clear boundaries are difficult to establish, both in scientific terms and in the public eye. For example, in 2011 a group of Non-Govermental Organisations (NGO'S) comprising 111 environmental, watchdog, and other organizations released a report with specific regulatory recommendations for new biological techniques for building and remaking organisms for research and commercial uses ranging from medicines to biofuels. These NGO's described synthetic biology as "an extreme form of genetic engineering" and called for a moratorium on its use.[137] More recently, two distinct groups of high profile scientists have called for a moratorium on editing germ line genome with CRISPR-Cas9 and zinc-finger nucleases.[138] In their *Nature* and *Science* articles, these two groups advised that research which produces heritable edits to the human genome must not proceed until the risks are better understood. The technologies in question have shown great potential as tools for selectively targeting genes or sections of DNA f or editing and could prove as revolutionary as recombinant DNA technology. Scientists worry that use of these technologies without a larger public debate may cause blind negative public perception concerning all possible applications of the technology. Editing of the human germ line is already illegal in several jurisditions and heavily regulated in others.[139] The patentability of such technologies is also subject to restrictions codified in the European Biotech Directive and recent applications in plant sciences carried out at the University of Copenhagen have stimulated a fierce international debate.[140]

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[136] Article 2 (2) *"'genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*" Article 2 (2) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106 , 17/04/2001 P. 0001 – 0039.

[137] 'The Potential Impacts of Synthetic Biology on the Conservation & Sustainable Use of Biodiversity: A Submission to the Convention on Biological Diversity's Subsidiary Body on Scientific, Technical & Technological Advice" Submitted by: The International Civil Society Working Group on Synthetic Biology Consisting of: Action Group On Erosion, Technology and Concentration (ETC Group), Econexus, Friends of the Earth USA, International Centre for Technology Assesment, The Sustainability Council of New Zealand. (2011), Available at: http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/cbdsynbiocsosubm.pdf (accessed 10 May 2015)

[138] Lanphier E, Urnov F, Haecker SE, Werner M, Smolenski J. Don't edit the human germ line. Nature. 519, 410-411 (2015); Baltimore D, Berg P, Botchan M, et al. A prudent path forward for genomic engineering and germline gene modification. ScienceDOI: 10.1126/science.aab1028

[139] Regarding Europe, see for example the restriction imposed by Article 13, Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention),

[140] Art. 6 (2) Biotech Directive. *Cf.* Gina Kolata , A Proposal to Modify Plants Gives GMO Debate New Life, The New York Times, May 28, 2015, available at: http://www.nytimes.com/2015/05/29/a-proposal-to-modify-plants-gives-gmo-debate-new-life.html?_r=0 (accessed 5 June 2015).

On the other hand: While Europe remains reticent in accepting the benefits and possibilities opened by plant science, crucial developments - such as population growth[141], the rapid development of the global south and the resulting increase in consumption - imply that more energy, food and raw materials will have to be produced by the industry and energy sectors with lesser occupation of soil surface.[142] Emerging technologies may offer new solutions and the acceptance of GMO's and emerging plant science may become instrumental in solving the major challenges that mankind will face throughout the 21th century.

6. Concluding remarks

The title of this paper encompasses two basic interrogations. *First*, we attempted to address the broader implications of the 'Broccoli' & 'Tomato' patent prosecution saga not only for the patentability of conventionally produced products, but also for genetic modified organisms and emerging technologies, such as synthetic biology and gene editing. *Second*, we considered whether this is really the end or just a mere prelude to further patent litigation in Europe. None of these questions has a clear answer. Technology is developing towards multidisciplinarity and convergence, while patent law struggles to characterise and establish legal boundaries.

In essence the decisions have confirmed that claims directed to novel and inventive plants obtained by methods which include breeding steps, as opposed to plant varieties, should in principle be allowable under the EPC, irrespective of whether claimed in a product per se or product-by-process format. Patent protection will only be categorically denied if the product is an individual "plant variety". This outcome is of course very positive news for patent applicants engaged in innovative plant breeding, and – as it was pointed out before – it may even affect the areas of GMO research and Synthetic Biology.

The systematically plausible solution found by the EPO has the merit of offering a way forward by allowing product and product-by-process claims even where the process may be – or may not -considered essentially biologic. Thus the debate concerning such delimitations becomes - at least on the EPO level - less imminent, which in turn provides certainty, innovation incentives and business perspectives for patent applicants. At the same time, however, the controversy over the merits of the EPO's approach is probably not over. Opposition to patentability of any technology that alters life forms remains very strong in Europe. This in combination with the systemic characteristics of the European patent system and a probably approaching CJEU decision leaves the distinct impression that "the thrill is not gone" and that prospective patentees may soon face new legal challenges looming over fruits and vegetables. From a practical perspective – and notwithstanding the more liberal EPO approach with regard to product by process claims - this also means that in order to minimize risks applicants should draft conventional product claims wherever possible.

More generally, this wide and complex context requires all stakeholders to engage in a public debate on the broader questions that are at stake here, such as: Who drives innovation and who benefits from it?; Why?; What are the long term effects of any decision on patent eligibility?; What are the alternatives?; and: What are the underlying reasons for the opposition against plan-related patents?; How should the opposition and potential dangers be adressed? Where are risks for public misunderstanding and conflations and how can these be dealt with?

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[141] It is estimated that by mid-century the earth population will reach around 9 billion people.

[142] Sharp, Philip A, "Presidential Address: Meeting global challenges: Discovery and innovation through convergence. Integrate biology, physics, engineering, and social science to innovate" 19 December 2014,VOL 346, ISSUE 6216 . Available at: <http://www.sciencemag.org/content/346/6216/1468.full.pdf?sid=c625dbb7-23ab-4606-a037-00921c80b7eb≥ (accessed May 10, 2015).

With regard to patent law, these debates should be based on correct information and understanding of patent law as a time-limited "negative exclusionary right", which must be differentiated from regulatory law. It also appears more important than ever to explain the exclusive effect of alternative or complementary forms of protection, such as plant variety rights, vis-à-vis patent rights. This requires to emphasize the systematic organization and rationale of other patentability requirements, such as novelty, inventive step and sufficient disclosure, as well as their mitigating effects of on the number and scope of claims that are actually being granted in the area. In this context, we believe it to be of vital importance to remember and communicate that patent law should not be misused to address or even solve problems that it was never created to solve. This notion is particularly important to us since it seems as if patent challenges are often used as a vehicle to express opposition against plant science and GMOs *as such*.

Be that as it may, in summary the Broccoli and Tomato patent saga is indeed a juicy tale of plant patenting. For the first time in 40 years the European Patent Office has accepted to conduct a consolidated sequel to previous consolidated decisions concerning the same inventions (albeight to amended claims). In the process the EBA closed the door to process claims for conventional biological methods, and opened the window for product and product-by-process claims. It is by any standart a spectacular finale. However, with regard to the varying national interpretations of the EU Biotech Directive, we believe that 'it ain't over' until the CJEU 'sings'. One may therefore ask whether we will soon be viewing a remake.

Post scriptum

After completion of this paper, the European Commission expressed that it did not share the opinion of the EPO's Enlarged Board of Appeal (cf. the Interpretative Notice from November 2016). Like several EU member states, such as France, Germany, Italy and Netherlands, the Commission found that under the EU Biotech Directive products obtained by essentially biological processes should not receive patent protection. This intervention by the Commission, the divergences between the interpretation of the EPC and the Biotech Directive, and the need for legal certainty and harmonization, led the EPO to stay ex officio all the proceedings in which the decision depended entirely on the patentability of a plant or animal obtained by an essentially biological process. Then, on June 29, 2017, the Administrative Council of the EPO decided to amend Rules 27 and 28 of the Implementing Regulation. According to these amendments products (animals or plants) obtained exclusively from essentially biological process are now effectively excluded from patentability. Notwithstanding that this contradicts the earlier decisions by the Enlarged Board of Appeal, these amendments apply to European patent applications filed on or after July 1, 2017, as well as to European patent applications and European patents pending at that time.

A first analysis of these changes is provided by Florica Rus at: http://ipkitten.blogspot.dk/2017/07/more-on-broccoli-tomatoes-and.html